Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effect of anesthesia induction with three medicinal compounds midazolam-nesdonal, propofol, and etomidate-propofol compared to thiopental alone on changes in heart rate and blood pressure during laryngeal mask application in eye surgery

Protocol summary

Study aim
Evaluation of the effect of anesthesia induction with three medicinal compounds midazolam-nesdonal, propofol, and etomidate-propofol compared to thiopental alone on changes in heart rate and blood pressure during laryngeal mask application in eye surgery

Design
A clinical trial without a parallel control group, double blind, randomized

Settings and conduct
In this randomized double-blind clinical trial, 128 patients who are candidates for general anesthesia cataract surgery are selected according to the study conditions, then the patients are randomly divided into four parallel groups. Then hemodynamic data including systolic and diastolic blood pressure, pulse rate, arterial oxygen saturation were recorded before tube placement and 1, 3 and 5 minutes after LMA administration. Duration of surgery and anesthesia is the duration of recovery in each group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who have indications for general anesthesia surgery and LMA surgery; Age over 18 years; ASA score or American Society of Anesthesiologists score 1 or 2; Consent to participate in the study; Exclusion criteria: If you have an underlying or systemic illness such as kidney failure, or uncontrolled heart failure, etc.

Intervention groups
We have four intervention groups. The first group was given midazolam-nesdonal combination, the second group propofol, the third group propofol and the fourth group thiopental.

Main outcome variables
Heart rate; Blood pressure

General information

Reason for update
The reason for the change is correction of writing and grammar of scientific and public titles sections.

Acronym

IRCT registration information
IRCT registration number: **IRCT20171030037093N27**
Registration date: **2020-01-07, 1398/10/17**
Registration timing: **prospective**

Last update: **2020-02-14, 1398/11/25**
Update count: **1**

Registration date
2020-01-07, 1398/10/17

Registrant information

Name
Sadra Ansaripour

Name of organization / entity
Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-16, 1398/11/27

Expected recruitment end date
2020-09-15, 1399/06/25

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of anesthesia induction with three medicinal compounds midazolam-nesdonal, propofol, and etomidate-propofol compared to thiopental alone on changes in heart rate and blood pressure during laryngeal mask application in eye surgery

Public title
Comparison of efficacy of 4 anesthesia methods on changes in heart rate and blood pressure during laryngeal mask application
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have indications for general anesthesia surgery and LMA surgery Age over 18 years ASA score or American Society of Anesthesiologists score 1 or 2 Consent to participate in the study
Exclusion criteria:
If you have an underlying or systemic illness such as kidney failure, or uncontrolled heart failure, etc.
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly divided into four parallel groups by blocking method using the Random Allocation software.
Blinding (investigator's opinion)
Double blinded
Blinding description
The method of blinding is that the drug groups are placed in numbered syringes by the researcher, giving each group its own number, and the drugs are covered by a black sheet having the same appearance.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahn University of Medical Sciences, Hezar jarib st, Isfahan
City
Isfahan
Province
Isfehan
Postal code
7346181746
Approval date
2019-11-27, 1398/09/06
Ethics committee reference number
IR.MUI.MED.REC.1398.448

Health conditions studied

1

Description of health condition studied
Adverse effect of general anesthetics
ICD-10 code
T41.205
ICD-10 code description
Adverse effect of unspecified general anesthetics

Primary outcomes

1

Description
Heart rate
Timepoint
Before intubation and 1, 3 and 5 minutes after LMA application
Method of measurement
Pulse oximetry

2

Description
Blood pressure
Timepoint
Before intubation and 1, 3 and 5 minutes after LMA application
Method of measurement
Barometer

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: The first group is given a combination of midazolam (0.04 mg / kg) - nesdonal (2.5 mg / kg).
Category
Treatment - Drugs

2

Description
Second Intervention Group: The second group is given propofol (5 mg / kg).
Category
Treatment - Drugs

3

Description
Third intervention group: The third group is given the combination of etomidate (0.1 mg / kg) - propofol (1 mg / kg).
Category
Treatment - Drugs

4

Description
Control group: The control group is given thiopental (2.5 mg / kg).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz Hospital
Full name of responsible person
Kamran Montazeri
Street address
Qods Square, Isfahan
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7346181746
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montazeri@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ziba Farajzadegan
Street address
Isfahan University of Medical Sciences, Hezar jarib Avne
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farajzadegan@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Kamran Montazeri
Position
Professor of Anesthesiology
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information about the main outcome can be shared.

When the data will become available and for how long
Start the access period 4 months after publishing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Use data to complete clinical trial studies

From where data/document is obtainable
Feiz hospital

What processes are involved for a request to access data/document
After the investigation of researcher request and presentation of required documents will be accessible.

Comments